

REMARKS

In the Office Action, claims 1, 2, 7, and 19-20 are rejected under 35 U.S.C. §102; and Claims 1,2, 7, 8 and 14-20 are rejected under 35 U.S.C. §103. Applicants believe that the rejections are improper for at least those reasons set forth below.

In the Office Action, claims 1, 2, 7, 19 and 20 are rejected under 35 U.S.C. §102 in view of U.S. Patent No. 4,244,378 ("*Brignola*") or U.S. Patent No. 5,535,785 ("*Werge*"). The Patent Office essentially asserts that *Brignola* or *Werge* discloses each and every feature of the claimed invention as defined by claims 1, 2, 7, 19 and 20. Applicants believe that *Brignola* and *Werge* are distinguishable from the claimed invention.

Of the pending claims, claims 1, 7 and 19 are the sole independent claims. Claim 1 recites a valve arrangement suitable for use with a rotary peristaltic pump and which is capable of allowing a flow of fluid in a first direction and capable of preventing the flow of fluid in a second direction. The valve arrangement includes a valve that has a cracking pressure of approximately 0.10 to about 0.20 bar wherein the valve includes a piston member with a stem and having a mushroom-shaped head which is deformable under pressure in a desired flow direction. Claim 7 recites a device for administration of at least one fluid to a patient. The device includes a valve arrangement with a piston member including a stem and having a mushroom-shaped head that is deformable under pressure in a desired flow direction and having a cracking pressure of approximately 0.10 to about 0.20 bar. The device further includes an inlet tube and an outlet tube. Claim 19 recites a device for controlling the flow of fluid from a container to a patient. The device includes a valve arrangement with a valve that is so constructed and arranged to prevent the flow of fluid to a patient at certain conditions, to allow the flow of fluid to a patient at a cracking pressure and to allow a certain level of a free flow of fluid to the patient. The valve includes a piston member with a stem and having a mushroom-shaped head which is deformable under pressure in a desired flow direction.

In contrast, Applicants believe that *Brignola* or *Werge* are deficient with respect to the claimed invention for at least a number of reasons. For example, *Brignola* provides a valve element in a chamber that is generally disc-like in shape. The valve element has a top face that contacts a rib at an upper wall of the chamber and a number of pedestals/legs at its bottom face. See, *Brignola*, Abstract, Fig. 4. Thus, clearly this is different than the valve arrangement as

claimed that includes, in part, a piston member with a stem and a mushroom-shaped head which is deformable under pressure in a desired flow direction.

In *Werge*, the primary focus of this reference relates to a Luer-activated check valve. More specifically, the check valve in *Werge* includes an upper housing (inlet) and a lower housing outlet fitted together to form a chamber in which a hat-shaped valve element is arranged. The valve element has a projecting flange that rests on annular valve seats of the upper housing, thus functioning as a seal. At the bottom side of the valve element, an annular extension or base is formed which may be compressed by a downwardly force. See, *Werge*, col. 4, lines 39-60, Fig. 4. Thus, the valve in *Werge*, like *Brignola*, is clearly different than the claimed valve arrangement that includes, in part, a piston member with a stem and mushroom shaped head as discussed above.

Based on at least these reasons, Applicants believe that *Brignola* or *Werge* fail to disclose the claimed invention as defined by claims 1, 2, 7, 19 and 20. Therefore, Applicants respectfully submit that the cited art fails to anticipate the claimed invention. Accordingly, Applicants respectfully request that the anticipation rejections with respect to claims 1, 2, 7, 19 and 20 be withdrawn.

In the Office Action, claims 1, 2, 7, 8 and 14-20 are rejected under 35 U.S.C. §103 in view of *Werge* and further in view of U.S. Patent No. 5,244,463 ("*Cordner*") and U.S. Patent No. 5,009,654 ("*Minshall*"). The Patent Office primarily relies on *Werge* and thus relies on *Cordner* and *Minshall* to remedy the deficiencies of same. Applicants believe that the obviousness rejection is improper and should be withdrawn.

Of the pending claims at issue, claims 1, 7, 14, 17 and 19 are the sole independent claims. Claim 1 recites a valve arrangement; claim 7 recites a device for the administration of at least one fluid to a patient; and claim 19 recites a device for controlling the flow of a fluid as discussed above. Claim 14 recites a method of providing a fluid to a patient. The method includes administering an effective amount of a fluid via a valve arrangement that includes a valve with a cracking pressure of approximately 0.10 to about 0.20 bar wherein the valve includes a piston member with a stem and having a mushroom-shaped head which is deformable under pressure in a desired flow direction. Claim 17 recites a method of treating a patient. The method includes administering a fluid from a container to a patient using a pump to propel the fluid via a valve arrangement. The valve arrangement includes a valve that has a cracking

pressure of approximately 0.10 to about 0.20 bar wherein the valve includes a piston member with a stem and having a mushroom-shaped head which is deformable under pressure in a desired flow direction.

In contrast, Applicants believe that the cited art, even if combinable, is distinguishable from the claimed invention. For example, the primary *Werge* reference is clearly deficient, at a minimum, with respect to a valve that includes, in part, a mushroom-shaped head as part of the piston member as claimed and discussed above. Indeed, the *Werge* reference merely provides a valve with a hat-shaped valve element that is mounted in a chamber formed by upper and lower housings as previously discussed.

In contrast, the claimed valve arrangement provides a valve that has a mushroom-shaped head which in a resting state blocks the channel at the inlet of the chamber and is restricted with its apex by a stopper. In this regard, the chamber is sealed in both directions, namely, the inlet and outlet directions. When the pressure exceeds the pressure in the chamber, the mushroom-shaped head deforms and unblocks the inlet of the chamber. Deformation of the mushroom-shaped head can also remove the apex of the mushroom head from the stopper, thus allowing flow through the outlet. By reducing the pressure below that of the chamber, the elastic mushroom-shaped head returns into its resting state and again blocks flow. Thus, the rest volume of fluid in the chamber is prevented from flowing back or forth and thus is captured therein.

Again, the valve in *Werge* fails to include a mushroom-shaped head as claimed. Moreover, the rest volume of fluid in the chamber as disclosed in *Werge* would readily pass through the outlet. Indeed, such a luer-activated check valve as disclosed in *Werge* effectively teaches away from the claimed valve arrangement. Therefore, the *Werge* reference, on its own, is clearly distinguishable from the claimed invention.

Further, Applicants do not believe that the Patent Office can rely solely on *Cordner* and *Minshall*, even if combinable, to remedy the deficiencies of *Werge*. Indeed, the Patent Office merely relies on *Minshall* for its alleged teaching regarding a rotary peristaltic pump with a check valve; and relies on *Cordner* for its alleged teaching regarding a pump with a check valve when delivering nutrition to a patient. Thus, Applicants do not believe that one skilled in the art would be inclined to modify *Werge* in view of the alleged disclosures with respect to *Minshall* and *Cordner* as relied on by the Patent Office.

Based on at least these reasons, Applicants believe that the cited art fails to disclose or suggest the claimed invention. Therefore, Applicants respectfully submit that the cited art, even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejection be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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